

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael Hensel, David William Holden and Jacquelin Shea

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For: *ATTENUATED SALMONELLA SP12 MUTANTS AS ANTIGEN CARRIERS*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including fourteen (14) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/763,620, filed March 2, 2001, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

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<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
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### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Dated: January 23, 2004

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			Application Number	Divisional of 09/763,620	
			Filing Date	January 23, 2004	
			First Named Inventor	Michael Hensel	
			Group Art Unit		
			Examiner Name		
Sheet	1	of	14	Attorney Docket Number	ICI 104 DIV

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,397,697		Lam, et al.	03-14-1995	
		5,527,674		Guerra, et al.	06-18-1996	
		5,618,666		Popoff, et al.	04-08-1997	
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FOREIGN PATENT DOCUMENTS								
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		Office. <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 92/01056		Institut Pasteur	01-23-1992		
		PCT	WO 93/04202		Washington University	03-04-1993		
		PCT	WO 94/26933		Leland Stanford Junior University	11-24-1994		
		PCT	WO 96/17951		RPMS Technologies, Ltd.	06-13-1996		

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		ADACHI, et al., "Isolation of <i>Dictyostelium Discoideum</i> Cytokinesis Mutants by Restriction Enzyme-Mediated Integration of the Blasticidin S Resistance Marker," <i>Biochem. Biophys. Res. Comm.</i> 205:1808-1814 (1994).	
		ALBUS et al. "Virulence of <i>Staphylococcus aureus</i> mutants altered in type 5 capsule production," <i>Infect. Immun.</i> 59:1008-1014 (1991).	
		ALDHOUS, "Fast Tracks to Disease Genes," <i>Science</i> 265:2008-2010 (1994).	
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		ARTIGUENAVE, et al., "High-efficiency transposon mutagenesis by electroporation of a <i>Pseudomonas fluorescens</i> strain," <i>FEMS Microbiol. Lett.</i> 153:363-369 (1997).	
		BAINTON, et al., "Immunity of children to diphtheria, tetanus, and poliomyelitis," <i>British Medical Journal</i> 1:854-57 (1979).	
		BLACK, et al., "Restriction enzyme-mediated integrated elevates transformation frequency and enables co-transfection of <i>Toxoplasma gondii</i> ," <i>Mol. Biochem. Parasitol.</i> 74:55-63 (1995).	
		BLASCO, et al., "Nitrate reductases of <i>Escherichia coli</i> : Sequence of the second nitrate reductase and comparison with that encoded by the <i>narGHJ</i> operon," <i>Mol. Gen. Genet.</i> 222:104-111 (1990).	
		BÖLKER, et al., "Tagging pathogenicity genes in <i>Ustilago maydis</i> by restriction enzyme-mediated integration (REMI)," <i>Mol. Gen. Genet.</i> 248:547-552 (1995).	
		BROWN et al. (1997) 19th Fungal Genetics Conference, 18-23 March 1997 (Asilomar Conference Centre, Pacific Grove, CA).	

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		BROWN, et al., "Molecular analysis of the <i>rfb</i> gene cluster of <i>Salmonella</i> serovar muenchen (strain M67): the genetic basis of the polymorphism between groups C2 and B," <i>Mol. Microbiol</i> 6:1385-1394 (1992).	
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		CHUANG et al. "Global regulation of gene expression in <i>Escherichia coli</i> ," <i>J. Bacteriol.</i> 175:2026-2036 (1993).	
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		COGLAN, "Bar codes to tag 'bad genes,'" <i>New Scientist</i> p. 18 (July 29, 1995).	
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		DUNYAKL, et al., "Identification of <i>Salmonella</i> pathogenicity island 2 (SPI2) genes in <i>Salmonella choleraesuis</i> using signature-tagged mutagenesis," <i>Abstracts of the 97<sup>th</sup> General Meeting of the American Society for Microbiology</i> 8-275, May 4-8, 1997.	
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		FITTS, "Development of a DNA-DNA Hybridization Test for the Presence of <i>Salmonella</i> in Foods," <i>Food Technology</i> pp. 95-102 (March 1985).	
		FREESTONE, et al., "Stabilized 17D strain yellow fever vaccine:dose response studies, clinical reactions and effects on hepatic function," <i>Journal of Biological Standardization</i> 5:181-186 (1977).	
		GAILLARD <i>et al.</i> (1986) "Transposon mutagenesis as a tool to study the role of hemolysin in the virulence of <i>Listeria monocytogenes</i> ," <i>Infect. Immun.</i> 52:50-55 (1986).	
		GALAN, et al., "Molecular And Functional Characterization Of The <i>Salmonella</i> Invasion Gene <i>invA</i> : Homology Of <i>InvA</i> To Members Of A New Protein Family," (1992).	
		GenBank Accession No. A51688 " <i>Salmonella typhimurium</i> " (1997).	
		GenBank Accession No. A51689 " <i>Salmonella typhimurium</i> " (1997)	
		GenBank Accession No. AF0208080 " <i>Salmonella typhimurium</i> pathogenicity island 2, partial sequence," (1998).	

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		GenBank Accession No. AJ224892 " <i>Salmonella typhimurium</i> ssaE, sseA, sseB, sscA, sseC, sseD, sseE, sscB, sseF, sseG, ssaG, ssaH, ssaI genes and partial ssaD, ssaJ genes," (1998).	
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		GenBank Accession No. U51927 " <i>Salmonella typhimurium</i> SpiR and SpiB genes, partial cds, and SpiC and SpiA genes, complete cds," (1996).	
		GenBank Accession No. X56793 " <i>S. enterica</i> (group B) rfb gene cluster," (1991).	
		GenBank Accession No. X61917 " <i>S. enterica</i> (group B) rfb gene cluster," (1991).	
		GenBank Accession No. X99944 " <i>S. typhimurium</i> ssaQ, ssaR, ssaT and ssaU genes," (1997).	
		GenBank Accession No. Y09357 " <i>S. typhimurium</i> ssaJ, ssaK, ssaL, ssaM, ssaV, ssaN, ssaO, ssaP, ssaQ genes," (1997).	
		GenBank Accession No. Z23278 " <i>E. coli</i> ClpX gene, complete cds," (1993).	
		GenBank Accession No. Z95891 " <i>Salmonella typhimurium</i> ssaA and ssaB genes," (1998).	

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		GROISMAN & OCHMAN, "How To Become A Pathogen," <i>Trends Microbiol.</i> 2:289-293 (1994).	
		GROISMAN & SAIE, "Salmonella Virulence: New Clues To Intramacrophage Survival," <i>Trends In Biochem. Sci.</i> 15:30-33 (1990).	
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		GUZMAN, et al., "Direct Expression of <i>Bordetella pertussis</i> Filamentous Hemagglutinin in <i>Escherichia coli</i> and <i>Salmonella typhimurium araA</i> ," <i>Inf. Immun.</i> 39:3787-3795 (1991).	
		GUZMAN, et al., "Expression of <i>Bordetella pertussis</i> filamentous hemagglutinin in <i>Escherichia coli</i> using a two cistron system," <i>Microbiol. Pathogenics</i> 12:383-389 (1992).	

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		GUZMÁN, et al., "Use of Salmonella spp carrier strains to delivery Bordetella pertussis antigens in mice using the oral route," in <i>Biology of Salmonella</i> (Cabello, et al., eds.) Plenum Press: New York, NY (1993).	
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		HOLDEN, "The type III secretion system of <i>Salmonella</i> pathogenicity island 2," <i>FEBS Advanced Course - Protein Export and Assembly in Bacteria</i> , Lunteren, The Netherlands (1998).	

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		HOLLAND, et al., "Tn916 Insertion Mutagenesis In Escherichia Coli And Haemophilus Influenzae Type b Following Conjugative Transfer," <i>J. Gen. Microbiol.</i> 138:509-515 (1992).	
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		LEE, "Type III secretion systems: machines to deliver bacterial proteins into eukaryotic cells?" <i>Trends Microbiol.</i> 5(4): 148-156 (1997).	
		LEE & FALKOW, "Isolation of Hyperinvasive Mutants of Salmonella," <i>Methods Enzymol.</i> 265:531-545 (1994).	
		LEVINE, et al., "Salmonella vaccines" in <i>New Antibacterial Strategies</i> (Neu, HC, ed.), pp. 89-104, (Churchill Livingstone:London, 1990).	
		LEVINE, et al., eds., "Attenuated Salmonella as a live vector for expression of foreign antigens," in <i>New Generation Vaccines</i> , 2 <sup>nd</sup> ed., Marcell Dekker: New York, Chapter 27, pp. 331-361 (1997).	

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		First Named Inventor	Michael Hensel
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	ICI 104 DIV
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		LISITSYN, et al., "Cloning The Difference Between Two Complex Genomes," <i>Science</i> 259:946-951 (1993).	
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		MILLER, et al., "A Two-Component Regulatory System (phoPphoQ) Controls Salmonella Typhimurium Virulence," <i>Proc. Natl. Acad. Sci. USA</i> 86:5054-5058 (1989).	

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		MILLER, et al., "Isolation Of Orally Attenuated Salmonella Typhimurium Following TnphoA Mutagenesis," <i>Infection Immun.</i> 57:2758-2763 (1989).	
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		PASCOPELLA, et al., "Use Of In Vivo Complementation In Mycobacterium Tuberculosis To Identify A Genomic Fragment Associated With Virulence," <i>Infection Immun.</i> 62:1313-1319 (1994).	
		PELLCIC et al. "Genetic advances for studying Mycobacterium tuberculosis pathogenicity," <i>Molecular Microbiology</i> 28:413-420 (1998).	

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		PIATTI, et al., "Cloning and Characterization of <i>S. typhi</i> ," Societa Italiana di Microbiologia Medica Odontoiatrica e Clinica '93 (Translation), p. 82.	
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		RÜSSMAN, et al., "Delivery of epitopes by the <i>Salmonella</i> type III secretion system for vaccine development," <i>Science</i> 281: 565-568 (1998).	
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		WOOLLEY et al. "Transfer of Tn1545 and Tn916 to Clostridium acetobutylicum," <i>Plasmid</i> 22:169-174 (1989).	

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